

6. (Amended). A capsule formulation comprising an antihypertensive, antiischaemic or angina - alleviating effective amount of the besylate salt of amlodipine as claimed in claim 1 in admixture with excipients.

8. (Amended). A capsule formulation as claimed in claim [1] wherein the excipients comprise microcrystalline cellulose, dried maize starch and magnesium stearate.

9. (Amended). A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina - alleviating effective amount of the besylate salt of amlodipine for parenteral administration.

Cancel claim 12.

REMARKS

The claims have been amended to correct deficiencies contained in the parent application.

The parent application, of which this application is a continuation, has been rejected under 35 U.S.C. 103 over Campbell, et al., U.S. 4,572,909, in view of Spiegel, et al., U.S. 4,032,637 and/or Schmidt, et al., U.S. 3,816,612.

Applicants traverse this rejection on the grounds that the ancillary references and the main reference were improperly combined. Neither Spiegel or Schmidt teach salts of compounds which are antihypertensive agents or compounds remotely resembling dihydropyridines; hence, their teachings are outside the scope of the present invention, and there is no evidence for combining these references. The In re Fine decision (CAFC 1988 5 USPQ 2d 1596) ruled that this type of improper combining of references leading to an "obvious to try" based-rejection is unacceptable.


Further, the attached Rule 132 Declaration provides information that demonstrates that the besylate salt of amlodipine possess all the desired characteristics necessary for a medicinal agent. While besylate salts have been employed

as pharmaceutically acceptable salts, it is not obvious that only the besylate salt of amlodipine would have all the necessary properties for a commercial product.

Finally, the reference provided by the Examiner, in the parent application (J. Pharm. Sci., 66, 1 (1977)) states on page 1, column 1, lines 1-6 of the first paragraph of the text, "The Chemical, biological, physical, and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form. Choosing the appropriate salt, however, can be a very difficult task, since each salt imparts unique properties to the parent compound" and in the Conclusions, page 16, line 5, "At present, selecting a salt form that exhibits the desired combination of properties is a difficult semiempirical choice." These statements lead one skilled in the art to conclude that the besylate salt of amlodipine is a unique compound and not an obvious one as stated by the Examiner.

A favorable consideration of the claims of the present continuation application is solicited.

Respectfully submitted,


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